

## REMARKS

With this response, Claims 1-28 are pending in the present application. Claim 29 has been canceled. Claims 1-28 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,616,765 to Castro et al.

Applicant believes that the claims, as previously presented, are patentably distinct over Castro for at least the reasons originally asserted in Applicant's August 9, 2006 Response. Further, the Applicant does not acquiesce to the rejections in the Final Office Action. However, to expedite allowance and further prosecution, the Applicant has amended claims 1 and 27 despite Applicant's continued belief that the previously presented claims are patentably distinct.

Applicant respectfully maintains that the claims are patentable over Castro for at least the following several reasons.

**I. Claims 1-15 And 27-28 Are Patentably Distinct Because Castro Fails To Disclose Or Suggest At Least Unassisted Gravitational Flow**

Although Applicant believes that the claims, as previously presented, are patentably distinct over Castro, Applicant nevertheless submits proposed amendments to expedite allowance, asserting that claims 1-15 and 27-28, as amended, are patentably distinct for at least the reason that Castro does not suggest or disclose at least the step of "gravitationally depositing the coating material from the slide surface onto the surface of the medical device by unassisted gravitational flow," as claimed in independent claims 1 and 27. Rather, Castro at least utilizes coating deposition methods other than unassisted gravitational fluid flow of the coating to deposit coating onto the surface of the medical device: "[d]elivery [of coating material] can be achieved passively via capillary action," or "[a]lternatively, delivery can be achieved actively by applying a pressure p to [the coating material] as depicted in Fig. 3A." See Castro, col. 8:12-16. In other words, Castro describes coating methods that are independent of gravity which utilize

non-gravitational capillary action or externally pressurize the fluid by applying “[c]ontinuous air pressure,” “bursts of air pressure,” or “acoustic, ultrasonic, fluid, or any other forms of pressure,” *see* Castro, col. 8:16-22, thereby allowing the syringe-type device of Castro to overcome the force of gravity. Accordingly, Applicants submit that Castro does not disclose at least the limitation, “gravitationally depositing the coating material from the slide surface onto the surface of the medical device by unassisted gravitational flow.”<sup>1</sup>

## II. Castro Teaches Away From Unassisted Gravitational Flow

In addition, there is no suggestion or motivation provided in Castro to modify the syringe-type dispenser of Castro to allow gravitational deposition of the coating material because Castro teaches away from using unassisted gravitational flow in depositing the coating material from the slide surface onto a medical device. As described above, the syringe-type device of Castro describes deposition methods that allow it to overcome gravity. *See* Castro, col. 8:12-22. Indeed, dispenser assembly 22 of Castro can be rotated (as shown by direction arrow 40 of Fig. 3F) such that orifice 28, through which coating material is dispensed, can be positioned in an upwards direction, thereby necessitating non-gravitational deposition methods, such as the application of capillary action or external pressure. *See* Castro, col. 8:41-44; Fig. 3F.

Furthermore, there can be no motivation to modify Castro because the proposed modification would change the way Castro operates. *See* MPEP 2143.01 (VI) (no motivation to combine where the “suggested combination would require a substantial reconstruction and redesign of the elements shown in the primary reference as well as a change in the basic principle under which the primary reference’s construction was designed to operate”).

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<sup>1</sup> Applicant respectfully submits that the proposed modification regarding “gravitational flow” does not require a new search nor raise new matter because the proposed amended language was previously, and continues to be, contained in other limitations of the claims (*e.g.*, “a slide surface adapted to facilitate gravitational fluid flow on the slide surface”).

Additionally, there can be no motivation because modifying the syringe-type device of Castro would render it unusable for its intended purpose of depositing coating material in a manner that can overcome the forces of gravity. *See* MPEP 2143.01 (V) (“If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.”).

### **III. Claims 1-28 Are Patentably Distinct Because Castro Fails To Disclose Or Suggest At Least An Outlet Through Which Coating Is Dispelled Onto A Slide Surface.**

In response to the Applicant’s previous remarks regarding the failure of Castro to suggest or disclose an outlet orifice in the step of “dispelling the coating material through the outlet orifice onto the slide surface” of the coating head, as previously presented in independent claims 1, 16 and 27 (*see* Applicant’s 8/9/06 Response, p. 7), the Final Office Action now asserts that the outlet orifice can be found on reservoir 24. *See* Final Office Action, p. 3 (“The examiner would argue that there necessarily must be an opening on reservoir 24 to fill it, in other words, an orifice with which the coating material enters reservoir 24.”)

As an initial premise, the Final Office Action now evidently considers the “opening on reservoir 24” to constitute both the “inlet” and the “outlet orifice” structures claimed in claims 1, 16 and 27. *See* Final Office Action, p. 3 (“Wherever the coating 10 enters the dispenser 22 can be considered an inlet orifice” and “there necessarily must be an opening on reservoir 24 to fill it, in other words, an orifice with which the coating material enters reservoir 24.”) Accordingly, Castro fails to disclose or suggest at least one of these structures (the inlet or the outlet orifice) of the slide coating head.

In addition to the above shortcoming, Castro also fails to disclose or suggest at least the limitation of “dispelling the coating material through the outlet orifice onto the slide surface” because, notwithstanding the Examiner’s characterization of the “opening on reservoir 24” as

both an inlet and outlet orifice, this opening through “which the coating material enters reservoir 24” does not dispel coating onto a slide surface because the “opening on reservoir 24” is not proximal to the inner wall of syringe nozzle 26.<sup>2</sup> Rather, the “opening on reservoir 24” allows coating material to enter the intermediary reservoir, which has no “slide surface adapted to facilitate gravitational fluid flow” as claimed. As seen in Figure 1, any “opening on reservoir 24 [through] which the coating material enters reservoir 24” is distal to the inner wall of nozzle 26, and accordingly cannot dispel coating fluid onto the asserted slide surface. Thus, Castro does not at least disclose the step of “dispelling the coating material through the outlet orifice onto the slide surface” of the coating head, as claimed in independent claims 1, 16 and 27.

Furthermore, there is no suggestion or motivation provided in Castro to modify the syringe-type dispenser of Castro to add the structural feature of another orifice proximal to the sloping inner wall of syringe nozzle 26, or the step of dispelling coating through an outlet surface onto a slide surface, nor does the Office Action point to any.

**IV. Claims 16-26 Are Patentably Distinct Because Castro Fails To Disclose Or Suggest At Least The Claimed Orientation Of Slide Surfaces Or The Formation Of A Multi-Layer Coating On A Slide Surface.**

In response to the Applicant’s previous remarks regarding the failure of Castro to suggest or disclose at least the step of “flowing the second coating material down the second slide surface, wherein the second slide surface is oriented relative to the first slide surface such that the second coating material flows on top of the first coating material on the first slide surface forming a multi-layer coating material having a layer of second coating material above a layer of first coating material,” as previously presented in independent claim 16 (*see* Applicant’s 8/9/06 Response, p. 8), the Final Office Action points to two passages in Castro. *See* Final Office

<sup>2</sup> The Office Actions maintain the inner wall of syringe nozzle 26 is a slide surface, although Applicant disagrees with the characterization. *See* Office Action, p. 3 (“Although the ’765 does not describe the nozzle as a slide coating head, the coating material does slide down the inside of nozzle 26 before reaching the prosthesis 12.”)

Action, p. 3. However, neither passage disclose or suggest a plurality of slide surfaces oriented in such a way to form a multi-layer coating material on a slide surface. In fact, neither passage say anything about the relative orientation or positioning of the dispenser assemblies, nor the formation of a unitary, multi-layer coating material on a slide surface (as opposed to the formation of a multi-layer coating on a medical device surface).

The first citation (Castro, col. 17:61-68) that the Final Office Action points to reveals nothing about the orientation of a plurality of dispenser assemblies. It merely states that two coating compositions may be deposited concurrently, which the office action apparently reads as inherently disclosing both the claimed orientation and the formation of a multi-layer coating on a slide surface. The Applicant respectfully disagrees.

As an initial premise, the cited passage in Castro does not disclose anything about forming a multi-layer coating composition on a slide surface. Rather, it states that the deposition of two separate coating compositions “onto [a] prosthesis” (not a slide surface) can occur concurrently. Concurrent deposition can be achieved by using two dispenser assemblies operating from opposite ends of the prosthesis depositing separate single-layer coatings simultaneously. The cited passage nowhere describes or requires relative orientation of the two dispenser assemblies to form a multi-layer coating material on a slide surface. Accordingly, Castro fails to disclose or suggest at least the orientation of a plurality of dispenser assemblies in any manner, much less suggest or motivate one of skill in the art to orient a plurality of dispenser assemblies in such a way to result in “forming a multi-layer coating material having a layer of second coating material above a layer of first coating material on a slide surface.”

Further, to the extent that the Examiner reads concurrent deposition as inherently disclosing both the claimed orientation and formation of a multi-layer coating, the Applicant

respectfully asserts that the Examiner has not supplied any “basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flow from the teachings of the applied art.” M.P.E.P. § 2112, IV (emphasis in original). Applicants respectfully point out that “[t]o establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted); *see also Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)). Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic may occur in the prior art does not establish the inherency of that result or characteristic.

Here, it has not been shown that the step of “flowing the second coating material down the second slide surface, wherein the second slide surface is oriented relative to the first slide surface such that the second coating material flows on top of the first coating material on the first slide surface forming a multi-layer coating material having a layer of second coating material above a layer of first coating material,” would necessarily flow from the cited passage in Castro describing concurrent deposition. Concurrent deposition of two coating materials by two separate dispenser assemblies in Castro does not require relative orientation of the two dispenser assemblies to form a multi-layer coating material on a slide surface. Rather, as discussed above, concurrent deposition involves operation of two dispenser assemblies depositing separate single-layer coatings simultaneously onto a medical device. Accordingly, this step does not necessarily flow from the recited passage in Castro. Moreover, the fact that the “second composition may be

deposited concurrently” (*see* Final Office Action, p. 3) is not sufficient to show inherency.

Inherency may not be established by probabilities or possibilities. *In re Robertson*, 169 F.3d at 745. Applicant respectfully maintains that the doctrine of inherency cannot supply the missing step. *See* M.P.E.P. § 2112.

The second passage (Castro, col. 18:33-48) that the Final Office Action points to fares no better. It too fails to disclose or suggest a plurality of slide surfaces oriented in such a way to form a multi-layer coating material on a slide surface. In fact, it teaches away from any formation of a multi-layer coating material on a slide surface. Rather, the passage describes depositing a first coating on the medical device surface and then depositing a second subsequent coating on the medical device. For example, the specification states that “[i]n one such embodiment, first composition 10 is deposited on prosthesis 12 as shown in Fig. 14A. Second composition 80 is then deposited to at least partially cover first composition 10 as depicted in Fig. 14B.” *See* Castro, col. 18:35-39. The remainder of the cited passage similarly recites depositing a first coating and then depositing a second coating. *Id.* col. 18:39-48. Thus, this passage also fails to support Examiner’s contention that Castro discloses or suggests the claimed orientation and the formation of a multi-layer coating on a slide surface.

Accordingly, for at least the reasons stated above, Applicant respectfully submits that claims 16-26 are patentable over the Castro reference.

**V. Claims 16-26 Are Patentably Distinct Because Castro Fails To Disclose Or Suggest Depositing A Multi-Layer Coating Onto The Surface Of A Medical Device**

Castro does not suggest or disclose at least the step of “depositing [a] multi-layer coating material onto the surface of the medical device,” as previously presented in claim 16. Rather, as discussed above, Castro describes depositing a first single-layer coating on a medical device surface, and then depositing a second, subsequent single-layer coating on the medical device, *see*

Castro, col. 18:35-48, or depositing the separate single-layer coatings concurrently or simultaneously. *See* Castro, col. 17:61-68. Thus, Castro does not disclose at least the step of “depositing multi-layer coating material onto the surface of the medical device,” and for this independent reason, claims 16-26 are patentably distinct over Castro.

#### **VI. The §103 Rejections Of Claims 6-8 And 24-25 Are Improper**

Finally, in response to the Applicant’s previous remarks regarding the failure of Castro to suggest or disclose a plurality of plates as claimed in dependent claims 6-8 and 24-25, the Final Office Action states that “plate may be defined as any surface within the reservoir 24, and therefore reservoir 24, nozzle 25 [sic], and orifice 26 [sic] may be considered to consist of a plurality of surfaces or plates.”

Foremost, the Examiner has issued an improper § 103 rejection by contending that it is obvious that a reference discloses a particular feature. A reference either discloses, or fails to disclose, a particular feature. Submitting that the existence of a feature in a reference is obvious is not proper under § 103.

If the Examiner is impliedly taking official notice of a teaching or suggestion of plates, then Applicant respectfully traverses this implied taking and officially requests that the Examiner provide documentary evidence of this teaching or suggestion in the next action if this rejection is to be maintained. M.P.E.P. § 2144.03.

Regardless, as depicted throughout the figures of Castro, nozzle 26 is part of a unitary syringe structure 22. Castro does not disclose or suggest a nozzle comprising of separable plates, let alone disclose assembling the plates to form an outlet orifice between the plates, as claimed in claims 7 and 25. Furthermore, there is no suggestion or motivation provided in Castro to modify the syringe-type dispenser of Castro to add the structural feature of plates, nor does the Office



Action point to any. Accordingly, Applicant respectfully submits that claims 6-8 and 24-25 are independently patentable over the Castro reference for at least this reason as well.

**CONCLUSION**

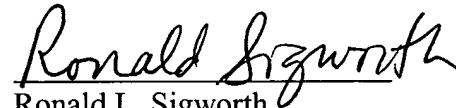
In view of the preceding remarks, the Applicant respectfully submits that each of the pending claims is in condition for allowance and, therefore, requests reconsideration and allowance of all pending claims.

The Commissioner is hereby authorized to charge Kenyon & Kenyon LLP Deposit Account No. 11-0600 for any applicable fee.

Should the Examiner require any additional information regarding this Response, the Examiner is invited to contact the undersigned at (202) 220-4200.

Respectfully submitted,

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